https://chemicalwatch.com/66716/american-chemistry-council-defends-epa-secret-science-proposal

American Chemistry Council defends EPA 'secret science' proposal

Trade body backs non-linear models, increased transparency

10 May 2018 / Data, Exposure modelling, United States

The American Chemistry Council has defended aspects of the US EPA's new science transparency proposal that have come under fire from NGOs.

Formally issued late last month, the agency's proposed rule on "secret science" seeks to allow increased transparency and public validation of studies underpinning agency regulatory decisions.

Among other provisions, it proposes to "increase transparency of the assumptions underlying dose response models". NGOs have raised the alarm that discarding default linear dose models will remove health-protective assumptions and "invite literally an infinite number of model options" on which the agency can base its decision.

But the ACC argues that the EPA has this aspect of the policy right. "For far too long and far too often EPA has relied on default linear dose-response models that have frequently resulted in inflated risk estimates," the trade group said in a blog post.

These, it says, create "misperceptions and confusion about true risks and can lead to unwarranted and costly risk management decisions."

Default linear models concerns

The ACC told Chemical Watch that an example of this occurred with the draft Integrated Risk Information System (IRIS) risk assessment of formaldehyde. It says the programme's use of "overly conservative default assumptions" led it to proposing a cancer risk value at 0.008 parts per billion – a level significantly lower than the 0.8 to 8.0 ppb reported to naturally occur in humans.

The IRIS formaldehyde assessment prompted a scathing review from the National Academy of Sciences (NAS) in 2011. And industry has continued to question the science underlying the programme's conclusion.

The ACC also pointed to the case of 1,4-dioxane, in which the EPA's use of a default linear approach served as the basis for a drinking water guidance as low as 0.35ppb. The trade group said that Health Canada, the EU and other authoritative bodies have concluded the substance acts by a non-linear mechanism, resulting in a drinking water guidance of 350ppb.

The EPA's plan to consider non-linear models is not satisfying an industry 'ask', added the ACC. Instead, it is "simply a recognition by EPA that old default assumption may not always represent the most up to date science".

Transparency

Separately, the ACC's formaldehyde panel has taken aim at critics who have suggested that industry groups would attempt to use the EPA's new policy to discredit legitimate studies underpinning health protections.

"Industry does not seek access to research to discredit it nor to limit regulation," said the formaldehyde group's blog post.

"In order to help improve public confidence in the decision-making process, it is critical data be made available in a timely and transparent way to ensure decisions are based on scientifically defensible information," the post said.

ACC Blog https://blog.americanchemistry.com/2018/05/epas-proposed-rule-on-transparency-in-regulatory-science-gets-it-right-when-it-comes-to-the-best-available-science-and-non-linear-modeling-approaches/

EPA's proposed rule on transparency in regulatory science gets it right when it comes to the best available science and non-linear modeling approaches

By American Chemistry on May 3, 2018 in Policy

At ACC we're still doing a deep dive in our review of EPA's recently proposed rule: Strengthening Transparency in Regulatory Science. We look forward to submitting comments to help the agency ensure the final rule increases transparency and public confidence in the agency's regulations while protecting personal privacy, confidential business information, proprietary interest and intellectual property rights. That said, one thing we already know they got right is the rule's focus on dose response data and models.

For far too long and far too often EPA has relied on default linear dose-response models that have frequently resulted in inflated risk estimates. These inflated risks create misperceptions and confusion about true risks and can lead to unwarranted and costly risk management decisions. The good news is that EPA's proposed rule calls on agency scientific staff and decision makers to give appropriate consideration to non-linear models or threshold models (i.e. dose models that show a level of exposure to a substance below which no harm is expected to occur). In other words, to use the best available science by presenting non-linear modeling approaches consistent with the available data and scientific understanding of endogenous exposures and mode of action, in lieu of, or at a minimum in addition to, the linear default.

"EPA shall evaluate the appropriateness of using default assumptions, including assumptions of a linear, no-threshold dose response, on a case-by-case basis. EPA shall clearly explain the scientific basis for each model assumption used and present analyses showing the sensitivity of the modeled results to alternative assumptions. When available, EPA shall give explicit consideration to high quality studies that explore: A broad class of parametric dose-response or concentration-response models; a robust set of potential confounding variables; nonparametric models that incorporate fewer assumptions; various threshold models across the dose or exposure range; and models that investigate factors that might account for spatial heterogeneity."

The proposed provision has been characterized in some corners of the environmental NGO blogosphere as granting industry an "ask." Wrong. It's simply a recognition by EPA that old default assumptions may not always represent the most up to date science. Notably, it is an approach a strong bi-partisan majority of Congress supported in the 2016 amendments to Section 26 of the Toxic Substances Control Act: When it comes to the science, EPA should "show its work."

Backed by the best available 21st century science, ACC has long advocated for use of non-linear, threshold models in cases where available data and scientific understanding support such models. In fact mode of action and non-linear models are integral components in our well-known Risk Principles, found here and here.

UTILIZE MODERN SCIENTIFIC INFORMATION AND TOOLS RATHER THAN CONTINUING TO RELY ON OUTDATED ASSUMPTIONS: Reliance on defaults should be minimized. In many cases, government hazard and risk assessment programs rely on assumptions and default approaches developed in the 1970s ***[i.e., linear, no-threshold dose response].*** *Today's scientists and health professionals have a wealth of knowledge including 21st-century understanding of how the human body works and the way chemicals interact with the body* ***[i.e., mode of action and non-linear dose response****] and the environment at different levels of exposure. This modern-day knowledge must be applied when determining chemical safety.*

CHARACTERIZE HAZARDS AND RISKS FULLY AND ACCURATELY: Hazards and risks must be objectively characterized and presented in a manner understandable to stakeholders and risk managers. The characterization should provide a full picture of what is known and what has been inferred and should also present results based on alternative plausible assumptions ***[i.e., not just the default, but also scientifically plausible modes of action and non-linear dose response]****. When a screening level assessment indicates potential concern, prior to initiating additional risk management actions, a refined assessment should be conducted to more accurately determine hazards or risks. When going beyond screening level, assessments should include central estimates and ranges; it is not sufficient to rely on theoretical maximum exposure estimates to characterize potential risk.*

EPA got it right. We welcome this aspect of the Strengthening Transparency in Regulatory Science proposed rule and look forward to working with the agency to help ensure that it continues to recognize and act on advances in scientific knowledge and the best available, most relevant scientific data and integrates this into its regulatory decision making processes.

ACC FA Panel Blog https://blog.americanchemistry.com/2018/05/an-open-letter-to-ee-news/

An open letter to E&E News

By American Chemistry on May 2, 2018 in Media

The American Chemistry Council (ACC) Formaldehyde Panel (the Panel) believes increasing transparency and public confidence in government regulations, while protecting personal privacy, confidential business information, proprietary interest and intellectual property rights, is of utmost importance. Although some have argued this opens the door for industry to go after important studies that underpin

public health protections, the Panel begs to differ. Changes happening at the EPA are bolstering this concept, ensuring independent experts can have access to the science supporting regulatory initiatives.

Predictably, we've seen an onslaught of various degrees from those that oppose Administrator Pruitt's initiative. Scott Waldman of E&E News recently interpreted industry's desire for open and transparent data—in his article "How Pruitt's Science Plans Might Help Industry Fight Rules"—as an effort to discredit science that underlies regulations that protect public health. This is untrue. Industry does not seek access to research to discredit it nor to limit regulation; rather Americans deserve to know that high quality science is the foundation of government regulations.

Take for example the case of formaldehyde. There have been claims over the years that formaldehyde causes leukemia. However, the weight of scientific evidence does not support a causal association between formaldehyde exposure and leukemia. Yet since 2010, several government agencies, including the EPA, have used a study known as the Zhang Study, to support incorrect conclusions that formaldehyde causes leukemia.

The Zhang Study failed to meet its own data quality standards and the scientific standard of reproducibility. For these very reasons, Dr. Goldstein and other scientists have repeatedly called for researchers to attempt to replicate the Zhang Study. Following these findings, industry took multiple steps to advocate redoing the Zhang Study in a different group of workers exposed to formaldehyde, however no such occupational settings with exposures as high as the original Zhang Study exist. Even if such an occupational setting was found, the same cross-sectional approach that was used for the Zhang Study would not be recommended. Instead a study which includes validated outcomes more predictive of leukemia than less specific-specific blood measures would be of a higher standard. In addition, industry has sent multiple letters to both the National Institute of Environmental Health Sciences (NIEHS) and EPA to suggest partnering to replicate the Zhang Study, with no response to our proposals.

Notably, in order to access data from the study to conduct a reanalysis, it took multiple years of requests to the National Cancer Institute (NCI) for the release of relevant data. Once the data were made available and reanalysis conducted, the data were found to have significant scientific shortcomings that called into question the original findings—a fact that regulators today would not have known if it weren't for the analysis of the raw data that pointed out the significant flaws of the study.

But Zhang is not the only example. There have been several examples in recent years where publicly-funded research data were not provided in a transparent or timely manner and erroneous evaluations and interpretations persisted. In one such instance, again after years of requests and negotiations, the underlying data from another NCI study were obtained and reanalyzed. In a publication by Checkoway et al. 2015, a fuller analysis and interpretations of the data determined that some of the original study conclusions were not supported and, most notable, that the study did not demonstrate a link between occupational formaldehyde exposure at any level and risk of acute myeloid leukemia (AML). The scientific quality of the Checkoway *et al.* reanalysis was acknowledged when the publication received the 2017 American College of Occupational and Environmental Medicine (ACOEM's) Journal of Occupational and Environmental Medicine (JOEM) Kammer Merit in Authorship Award.

In another call for data transparency and availability, it took nearly two years and multiple requests to the National Toxicology Program (NTP) for the release of a full study report on a key government-conducted rodent study finding no association with leukemia. The delay in revealing and communicating

accurate analyses and interpretations of these three studies materially contributed to the growing but erroneous belief that formaldehyde causes leukemia.

Dr. Goldstein of the University of Pittsburgh claims in Waldman's article that industry does not fund "new science to see whether this thing is right or wrong." He accuses industry of "waging a political and legal war, rather than focusing on research." Contrary to this claim, industry has diligently worked to support research that improves the understanding of formaldehyde; adds to the scientific evidence demonstrating that formaldehyde does not cause leukemia; and supports that there are clearly defined safe thresholds for formaldehyde exposure. Using state-of-the-art technologies, it is clear that inhaled formaldehyde does not reach the bone marrow (nor does it move beyond the nose). In fact, formaldehyde is naturally occurring. All of this information has been shared with EPA and made available in dozens of peer reviewed scientific publications. Formaldehyde is one of the most-well studied substances, thanks, in part to industry's commitment to generating new science.

Data availability and transparency are key components to ensuring that the best available and most relevant science underlies regulatory decision-making and protects public health. Yet many policymakers—not to mention the public at large—are left in the dark as to whether the science they are charged with interpreting to form public health regulations is sound.

Relying on the misleading findings as reported in the original Zhang Study for example has consequently led to flawed chemical assessment conclusions. Formaldehyde technologies however have broad roles in the economy, from the automotive to aerospace industries, providing thousands of jobs. The impact of poor science as the foundation for government regulation can be felt across the entire value chain, from manufacturer, to workers and finally the consumer.

In order to help improve public confidence in the decision-making process, it is critical data be made available in a timely and transparent way to ensure decisions are based on scientifically defensible information.

Sincerely,

The ACC Formaldehyde Panel